UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA

Jose Chung Luo, individually and on behalf of all similarly situated,

Plaintiff

v.

Spectrum Pharmaceuticals, Inc., et al.,

Defendants

Case No. 2:21-cv-01612-CDS-BNW

Order Granting in Part and Denying in Part Defendants' Request for Judicial Notice, Plaintiff's Motion to Strike, and Defendants' Motion to Dismiss Second Amended Complaint

[ECF Nos. 99, 101, 107, 114]

This is a class action securities lawsuit filed by plaintiff Jose Chung Luo against defendants Kurt A. Gustafson, Francois J. Lebel, M.D., Thomas J Riga, Spectrum Pharmaceuticals, Inc., and Joseph W. Turgeon on behalf of all persons and entities that purchased or otherwise acquired Spectrum Pharmaceuticals, Inc. ("Spectrum" or the "Company") common stock between March 7, 2018, and August 5, 2021. Luo brings claims pursuant to Sections 10(b), 20A, and 20(b) of the Securities Exchange Act of 1934 and Securities and Exchange Commission (SEC) Rule 10b-5, codified at 17 C.F.R. 10b-5. Second am. compl. ("SAC"), ECF No. 93 at 9. In November 2022, defendants moved to dismiss the amended complaint (ECF No. 55), which the court granted in part at a hearing on February 6, 2024 (Feb. 2024 order, ECF No. 82). Luo then filed a second amended complaint (ECF No. 93), which defendants now move to dismiss (ECF No. 99). The motion is fully briefed. ECF No. 104; ECF No. 112. In connection with their motion to dismiss, defendants also filed a request for judicial notice, which Luo opposes in part. ECF No. 101; ECF No. 106. Luo separately moved to strike part of the request for judicial notice. ECF No. 107. Both motions are fully briefed. ECF No. 108;

ECF No. 111; ECF No. 113.[1] For the reasons below, I grant in part and deny in part the request for judicial notice, grant in part and deny in part the motion to strike, and grant in part and deny in part the motion to dismiss.

I. Background

Spectrum is a small pharmaceutical company that makes money by purchasing the rights to late-stage developmental drugs with an aim to bring them to market. ECF No. 93 at 9. Spectrum's two primary developmental drugs during the relevant period were poziotinib ("Pozi"), a drug that purports to treat specific lung cancers, and Rolontis, a drug that purports to treat neutropenia, a side effect of chemotherapy. *Id.*

As developmental drugs, Pozi and Rolontis could not earn revenue for Spectrum unless and until the drugs gained Food and Drug Administration (FDA) approval. *Id.* Luo alleges that the survival of Spectrum depended on the approval of these drugs, and that because of the pressure, defendants attempted to rush the drugs through protracted clinical trials hoping to gain approval as soon as possible. *Id.* at 9–10. Spectrum allegedly spent $30 million or more per quarter on its trials and, to earn revenue, defendants sought additional cash through a sale of assets, a public offering, and multiple at-the-market offerings. *Id.* at 10. Luo alleges that to solicit interest for their fundraising efforts, defendants repeatedly materially overstated the status and progress of Pozi and Rolontis and withheld negative data and results from investors. *Id.*

A. Pozi

Luo alleges that Pozi underwent two clinical trials before it was ultimately denied approval by the FDA. The first was called the MD Anderson trial, beginning in March 2017 and ending in September 2018, where Spectrum attempted to secure breakthrough therapy

[1] Luo also moved for leave to file supplemental authority in support of the response to the motion. ECF No. 114. Because the authority is only persuasive and I find that Luo has sufficiently pled scienter for some of his claims, *see infra*, I deny this motion.

designation (BTD) approval for Pozi. *Id.* at 131.[2] The MD Anderson trial resulted in an objective response rate[3] (ORR) of forty-three percent, and the FDA ultimately did not approve Pozi for BTD. *Id.* The ZENITH20 trial began with cohort one (C1) in October 2017, involved a second cohort (C2), and ended with cohort three (C3) in 2020, with the final ORR for C1 at 14.8% and 27.8% for C3. *Id.* at 133, 135. Luo alleges that the FDA required an ORR of thirty percent or higher for Pozi to achieve approval, which it did not meet, so it was not approved by the FDA. *Id.* at 35.

Luo alleges that these Pozi clinical trials were performed on an "unmasked" basis, meaning that defendants had ready access to the trial data, and that such data demonstrated Pozi was not efficacious or safe enough to warrant FDA approval. *Id.* at 10. Rather than share this adverse information with investors, Luo alleges that defendants concealed it and instead cited misleading and outdated data, claiming they were "really confident" the FDA would approve the ineffective drug. *Id.* Luo also alleges that defendants claimed Pozi addressed a "huge unmet need" among lung cancer patients but misrepresented the then-existing standard of care. *Id.* Finally, Luo alleges that defendants claimed the side effects of Pozi were "in line" with competing products, when they were so "disabling" and "intolerable" for patients that many were forced to stop treatment before they completed the trial. *Id.*

B. Rolontis

Regarding Rolontis, Luo alleges that, when the FDA rejected Spectrum's first biologics license application (BLA) as inadequate, CEO Joe Turgeon falsely claimed that the company "voluntarily" withdrew the application for "administrative" reasons. *Id.* at 45. He further alleges that Turgeon misleadingly claimed that Spectrum was "absolutely ready" for the inspection at

[2] According to Luo, BTD is a fast-track designation, and "a drug qualifies for BTD only if the FDA determines it: (1) treats a serious condition; and (2) represents a 'substantial improvement' over existing therapies." ECF No. 93 at 35 (failing to cite to a source).

[3] The SAC defines "objective response rate" as the "[c]ommon metric for efficacy of cancer treatment that measures the proportion of patients whose tumor either disappears or reduces in size (higher ORR indicates more effective drug)[.]" *Id.* at 7.

its South Korean facility despite having failed its mock inspections multiple times, and despite the facility failing its actual inspection. *Id.* at 10–11.

Luo alleges that while defendants were misrepresenting Spectrum's products to everyday investors, they were enriching themselves by dumping their personal shares of Spectrum common stock. *Id.* at 11. For example, Luo alleges that just days before announcing that Pozi had failed its clinical trial, and with full knowledge of the deficient results, Turgeon sold nearly half of his shares in two large trades. *Id.*

Luo alleges that by the end of the class period, neither Pozi nor Rolontis were approved by the FDA and the price of Spectrum common stock had plummeted from $21.23 to $2.55 per share, never recovering and ultimately getting delisted at $1.03 per share on July 31, 2023. *Id.*

The court considers and groups Luo's claims in three categories: Luo's allegations that defendants: (1) misled investors about MD Anderson's trial of Pozi; (2) made misleading or false statements concerning the interim results of the ZENITH20 trial of Pozi; and (3) misled investors about its voluntary withdrawal of a BLA submission for Rolontis, and later about the Hanmi facility's readiness for FDA inspection.

II. Legal standard

A. Judicial notice

When ruling on a motion to dismiss, courts may look beyond the four corners of the complaint to documents incorporated by reference and matters subject to judicial notice. *Khoja v. Orexigen Therapeutics, Inc.*, 899 F.3d 988, 998 (9th Cir. 2018); *see also Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007). Documents incorporated by reference include those that "'for[m] the basis of the plaintiff's claim,'" or that a complaint refers "'extensively to,'" *Khoja*, 899 F.3d at 1002 (quoting *United States v. Ritchie*, 342 F.3d 903, 907 (9th Cir. 2003)), as well as documents that the complaint "necessarily relies" on, the authenticity and relevance of which are uncontested, *Coto Settlement v. Eisenberg*, 593 F.3d 1031, 1038 (9th Cir. 2010). Federal Rule of Evidence 201 authorizes a court to take judicial notice of matters that are "generally known" or

"can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201. Although "a court may take judicial notice of matters of public record without converting a motion to dismiss into a motion for summary judgment," "a court cannot take judicial notice of disputed facts contained in such public records." *Khoja*, 899 F.3d at 999.

B. Motion to strike

Pursuant to Rule 12(f) of the Federal Rules of Civil Procedure, the court may strike from a pleading "any redundant, immaterial, impertinent, or scandalous matter." Fed. R. Civ. P. 12(f). Additionally, it is well established that "[w]hether to grant a motion to strike lies within the sound discretion of the District Court." *Rimini St., Inc. v. Oracle Int'l Corp.*, 2019 WL 2358389, at *3 (D. Nev. June 4, 2019); *see Christian v. Mattel, Inc.*, 286 F.3d 1118, 1129 (9th Cir. 2002) ("The district court has considerable latitude in managing the parties' motion practice and enforcing local rules that place parameters on briefing."). Local Rule 7-2(g) dictates that: "A party may not file supplemental pleadings, briefs, authorities, or evidence without leave of court granted for good cause. The judge may strike supplemental filings made without leave of court."

C. Motion to dismiss

The Federal Rules of Civil Procedure (FRCP) require a plaintiff to plead "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). Dismissal is proper if the complaint lacks a "cognizable legal theory" or "sufficient facts alleged under a cognizable legal theory." *Balistreri v. Pacifica Police Dep't*, 901 F.2d 696, 699 (9th Cir. 1988). A pleading must give fair notice of a legally cognizable claim, and a plaintiff must proffer "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* This standard "asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.*

"At the pleading stage, a complaint stating claims under section 10(b) and Rule 10b-5 must satisfy the dual pleading requirements of [FRCP] 9(b) and the [Private Securities Litigation Reform Act (PSLRA)]." *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 990 (9th Cir. 2009). Rule 9(b) requires fraud claims to be pled with particularity, "but a pleading is sufficient under Rule 9(b) if it identifies 'the circumstances constituting fraud so that the defendant can prepare an adequate answer from the allegations.'" *Gottreich v. S.F. Inv. Corp.*, 552 F.2d 866 (9th Cir. 1977) (quoting *Walling v. Beverly Enters.*, 476 F.2d 393, 397 (9th Cir. 1973)). For its claims grounded in fraud, the SAC must allege the "who, what, where, when, and how" of the fraudulent conduct. *Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097, 1106 (9th Cir. 2003).

Further, when asserting a claim under the PSLRA of 1995, a plaintiff must plead the element of falsity with particularity. *Zucco*, 552 F.3d at 990–91; *Metzler Inv. GMBH v. Corinthian Colleges, Inc.*, 540 F.3d 1049, 1070 (9th Cir. 2008) ("The PSLRA has exacting requirements for pleading 'falsity.'"). The Ninth Circuit sets forth three ways for a plaintiff to establish falsity: (1) the statement is not actually believed, (2) there is no reasonable basis for the belief, or (3) the speaker is aware of undisclosed facts tending seriously to undermine the statement's accuracy.'" *City of Sunrise Firefighters' Pension Fund v. Oracle Corp.*, 527 F. Supp. 3d 1151, 1175 (N.D. Cal. Mar. 22, 2021) (quoting *City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Align Tech., Inc.*, 856 F.3d 605, 616 (9th Cir. 2017)). A plaintiff must plead specific facts to show how the statements at issue were false. *Metzler*, 540 F.3d at 1070; *see also Ronconi v. Larkin*, 253 F.3d 423, 434 (9th Cir. 2001) ("Plaintiffs' complaint was required to allege specific facts that show" how statements were false); *In re Arrowhead Pharm., Inc. Sec. Litig.*, 782 F. App'x 572, 574 (9th Cir. 2019). Moreover, to be actionable, a statement must be false at the time it was made. *Ronconi*, 253 F.3d at 430. "The fact that [a] prediction proves to be wrong in hindsight does not render the statement untrue when made." *In re VeriFone Sec. Litig.*, 11 F.3d 865, 871 (9th Cir. 1993).

At the dismissal stage, the court only considers the well-pled allegations in the plaintiff's complaint. *Twombly*, 550 U.S. at 555. Typically, when a party submits evidence outside the pleadings in a motion to dismiss, the court converts the motion to a motion for summary judgment and imposes Rule 56's standard. *Khoja*, 899 F.3d at 998. Finally, if the court grants a motion to dismiss for failure to state a claim, leave to amend should be granted unless the deficiencies of the complaint cannot be cured by amendment, rendering amendment futile. *DeSoto v. Yellow Freight Sys., Inc.*, 957 F.2d 655, 658 (9th Cir. 1992).

III. Analysis

A. Defendants' request for judicial notice and Luo's motion to strike

In connection with their motion to dismiss, defendants filed a request for judicial notice of the thirty-five exhibits attached to the declaration of John B. Lawrence. ECF No. 101. Luo objected in part to the request. ECF No. 106. Specifically, Luo objects to the court's consideration of exhibits 2, 26, and 35 as documents not referenced in the complaint and does not object to the court's consideration of exhibits 3–16, 18, 23, and 29 pursuant to the doctrine of incorporation, nor to exhibits 17, 19–22, 24–25, 27–28 and 33–34 pursuant to FRCP 201 as these documents were publicly filed and bear some relevance to the complaint. *See generally* ECF No. 106. Luo separately moves to strike exhibits 1 and 32. ECF No. 107. For the following reasons, I strike exhibit 1 and take judicial notice of exhibits 2–34, but not exhibit 35.

1. Exhibits 3–16, 18, 23, and 29

The parties agree that exhibits 3–16, 18, 23, and 29 are incorporated by reference by the complaint and thus judicially noticeable. Luo argues, however, that the court cannot "consider them for the truth of the matters asserted therein." ECF No. 106 at 7 (citing *Khoja*, 899 F.3d at 1003) ("[I]t is improper to assume the truth of an incorporated document if such assumptions only serve to dispute facts stated in a well-pleaded complaint.")). Defendants rebut that "[o]nce a document is deemed incorporated by reference, the entire document is assumed to be true for purposes of a motion to dismiss, and both parties—and the Court—are free to refer to any of its

contents." ECF No. 113 at 4–5 (quoting *In re NVIDIA Corp. Sec. Litig.*, 768 F.3d 1046, 1058 n.10 (9th Cir. 2014). The court agrees with both parties. In the Ninth Circuit, incorporation by reference is a doctrine that "treats certain documents as though they are part of the complaint itself." *Khoja*, 899 F.3d at 1002. A document may be incorporated by reference into a complaint "if the plaintiff refers extensively to the document or the document forms the basis of the plaintiff's claim." *Ritchie*, 342 F.3d at 908. However, "it is improper to assume the truth of an incorporated document if such assumptions only serve to dispute facts stated in a well-pleaded complaint" because there is a "prohibition against resolving factual disputes at the pleading stage." *Khoja*, 899 F.3d at 1003 (citing *In re Tracht Gut, LLC*, 836 F.3d 1146, 1150 (9th Cir. 2016) ("At the motion to dismiss phase, the trial court must accept as true all facts alleged in the complaint and draw all reasonable inferences in favor of the plaintiff.") and *Sgro v. Danone Waters of N. Am., Inc.*, 532 F.3d 940, 942, n.1 (9th Cir. 2008) (finding it proper to consider disability benefits plan referenced in complaint, but declining to accept truth of the plan's contents where the parties disputed whether defendant actually implemented the plan according to its terms)). With that authority in mind, the court proceeds as follows: (1) it takes judicial notice of exhibits 3–16, 18, 23, and 29 but (2) it does not consider said exhibits for the purpose of disputing the factual accuracy of Luo's non-conclusory allegations. In other words, the court considers these exhibits to analyze the false or misleading nature of the alleged false statement "in context." *In re Eventbrite, Inc. Sec. Litig.*, 2020 U.S. Dist. LEXIS 74651, at *24 (N.D. Cal. Apr. 28, 2020) ("[N]othing in *Khoja* prevents this Court from analyzing an alleged false statement in context."). In the manner outlined above, I take judicial notice of exhibits 3–16, 18, 23, and 29.

2. Exhibits 2, 26, and 35

Luo objects to the court's consideration of exhibits 2, 26, and 35 because they "are not referenced in the Complaint and are not proper subjects of judicial notice under Federal Rule of Evidence 201." ECF No. 106 at 2. I agree only with respect to exhibit 35 and take judicial notice of 2 and 26. Exhibit 2 is a conference call transcript from October 18, 2017, exhibit 26 contains

excerpts from Spectrum's 2017 Form 10-K, and exhibit 35 is the National Cancer Institute's definition of "open label study." Defs.' Exs. 2; 26; 35, ECF No. 100-2; ECF No. 100-26; ECF No. 100-35. Although dated before the relevant class period, as Luo points out, exhibits 2 and 26 contain content that bears relevance to the complaint and whose accuracy is not disputed. Thus, the court considers these exhibits as appropriate candidates for judicial notice. The National Cancer Institute's definition of "open label study," however, is not appropriate for judicial notice, particularly given defendants intend to use it to factually rebut Luo's allegations regarding defendants' access to the ZENITH20 data. ECF No. 113 at 5. Moreover, although the court is permitted to take judicial notice of dictionary definitions, without further context, the court cannot be certain that the National Cancer Institute is the authoritative source on the definition of an "open label study," or that the definition provided in exhibit 35 is considered exhaustive by the industry. Indeed, this document and factual arguments about the nature of the trials are best left for summary judgment and perhaps illumination by an expert. For those reasons, I take judicial notice of exhibits 2 and 26 but not 35.

3. Exhibits 17, 19–22, 24–25, 27–28, 30–31, and 33–34

Luo does not oppose defendants' request for judicial notice of exhibits 17, 19–22, 24–25, 27–28, 30–31, and 33–34 but disputes that the court can accept as true Individual Defendants' Forms 3 and 4 (Ex. 33) to show that their stock transactions were made pursuant to "tax withholding obligations" or 10b5-1 "trading plan[s]," particularly when the assertions were made by defendants themselves. ECF No. 106 at 7–8. Defendants rebut that the weight of authority in the Ninth Circuit counsels that "courts can consider 10b5-1 trading plans when evaluating allegations concerning scienter." ECF No. 113 at 5 (quoting *Pardi v. Tricida, Inc.*, 2022 WL 3018144, at *15 (N.D. Cal. July 29, 2022) (taking judicial notice of "SEC Form 4 filings"), *Habelt v. iRhythm Techs., Inc.*, 2022 WL 971580, at *6, 20 (N.D. Cal. Mar. 31, 2022) (relying on Form 4 in concluding sales pursuant to 10b5-1 plan did not support strong scienter inference)). I agree with Luo.

Judicial notice is appropriate only for facts "not subject to reasonable dispute because [they]: (1) [are] generally known within the trial court's territorial jurisdiction; or (2) can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201. Here, Luo disputes the truth of the forms' content in which defendants *themselves* made the assertion regarding whether their transactions were pursuant to "tax withholding obligations" or 10b5-1 "trading plan[s]." ECF No. 106 at 8–9 (citing Defs.' Ex. 30, ECF No. 100-33). Such doubt about self-reporting is particularly appropriate in a securities fraud case where the honesty of defendants is already in question. *See Maiman v. Talbott*, 2010 U.S. Dist. LEXIS 142712, at *20–21 (C.D. Cal. Aug. 9, 2010). Thus, I take judicial notice of exhibits 17, 19–22, 24–25, 27–28, 30–31, and 34. And, although I find exhibit 33 an appropriate subject for judicial notice given the nature of Luo's scienter allegations, I decline to consider it for the truth of the matter asserted. *Id.* ("Here, while it may be appropriate to judicially notice the existence of SEC filings and their contents, judicial notice should *not* be taken of the *truth* of their contents."). So I take judicial notice of exhibit 33 subject to the aforementioned limitation.

4. Exhibits 1 and 32

Luo argues that defendants submitted exhibits 1 and 32, both attorney-generated documents, for the purpose of presenting additional arguments outside of their motion to dismiss in violation of Civil Local Rule 7-2(g) and should thus be stricken. ECF No. 107. He further argues that defendants' attempt to characterize the charts as "helpful guide[s] to the Court" is hollow and the charts are instead just an improper attempt to circumvent the page limitations. ECF No. 111 at 3 (quoting ECF No. 108 at 1). Defendants argue that charts like these are routinely accepted and considered by courts in securities cases as providing the organizational work the court would have otherwise had to do. ECF No. 108. I agree with Luo concerning exhibit 1 and agree with defendants on exhibit 32.

Defendants were given a thirty-five-page limit in which to present their arguments as to which parts of the complaint should be dismissed and why. ECF No. 98. The chart in exhibit 1 contains an amalgamation of statements from the complaint accompanied by a column on the right labeled "Basis for Dismissal," which contains bullets for why each statement is purportedly dismissible, for reasons such as "no falsity," "opinion statement," "safe harbor," "puffery" and "no scienter." Defs' Ex. 1, ECF No. 100-1. This is not a helpful organizational chart—it is, as Luo argues, an extension of the dismissal argument that defendants wish the court to consider and resolve but apparently did not have space to specify in the brief itself. "Declarations . . . should not be used to make an end-run around the page limitations . . . by including legal arguments outside of the briefs." *King Cnty. v. Rasmussen*, 299 F.3d 1077, 1082 (9th Cir. 2002) (citing Fed. R. Civ. P. 56(e)); *see also Moussouris v. Microsoft Corp.*, 2018 U.S. Dist. LEXIS 112792, at *33–34 (D. Wash. June 25, 2018) ("The court agrees that Plaintiffs' chart should be stricken as improper legal argument outside the court-approved page limit."). For that reason, the court strikes exhibit 1.

Exhibit 32 is a different story. It simply compiles the individual defendants' stock trades contained in Appendix E to the SAC and adds two columns which transcribe from exhibit 33 whether defendants reported each trade as being pursuant to a Rule 10b5-1 Trading Plan, a tax withholding obligation, or both. Defs.' Ex. 33, ECF No. 100-33. Although the court will not consider exhibit 32 for the truth of matter asserted (given it is derived from exhibit 33), the chart itself is a useful and proper organization tool. *See Senne v. Kan. City Royals Baseball Corp.*, 315 F.R.D. 523, 570 (N.D. Cal. 2016) (refusing to strike charts that merely "identif[ied] the specific evidence that Defendants contend supports the general arguments set forth in their briefs"); *see also Okla. Firefighters Pension & Ret. Sys. v. Ixia*, 2015 WL 1775221, at *17 (C.D. Cal. Apr. 14, 2015) (considering chart of "the trading activity of the individual defendants" under Rule 1006 because it summarized "voluminous" data and the defendants also "submitted the underlying documents for consideration"). So I strike exhibit 1 and consider exhibit 32.

B. Motion to dismiss

Luo brings three counts: violations of 10(b) against all defendants (count I) and two counts of Section 20(a) violations against individual defendants (counts II and III). ECF No. 93 at 123–28. Defendants move to dismiss all three counts, arguing that Luo has failed to sufficiently allege either falsity or scienter. ECF No. 99. For the following reasons, I grant in part and deny in part defendants' motion to dismiss the 10(b) claim and deny defendants' motion to dismiss the Section 20(a) claims.

1. 10(b) claim (count I)

The basic elements of a Section 10(b) claim are: (a) a material misrepresentation or omission; (b) a connection with the purchase or sale of a security; (c) scienter; (d) economic loss; and (e) loss causation, i.e., a causal connection between the material misrepresentation or omission and the economic loss. *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 341–42 (2005); *Zucco*, 552 F.3d at 990. Under the PSLRA, a plaintiff alleging a Section 10(b) claim must "plead with particularity both falsity and scienter." *Zucco*, 552 F.3d at 990.

Defendants group Luo's alleged 10(b) misrepresentations regarding the MD Anderson trial for Pozi into three categories: (a) efficacy of existing treatments, (b) the target for FDA approval, and (c) supposed baseless optimism. ECF No. 99 at 6. They group the alleged misrepresentations regarding the ZENITH20 trial for Pozi into three categories: (a) expressing optimism for Pozi when defendants knew or recklessly disregarded that Pozi failed to meet its primary endpoint for efficacy, (b) referring to outdated results from the MD Anderson trial without disclosing the less promising results from C1, and (c) failing to disclose the impact adverse events (AEs) had on C1 patients and efficacy results. *Id.* at 21. Finally, defendants group the alleged misrepresentations about Rolontis into two categories: (a) misrepresenting the voluntary nature of Spectrum's withdrawal of its first BLA submission and (b) misleading investors in statements about the Hanmi facility's preparations for the FDA inspection. *Id.* at 34.

Defendants argue that Luo fails to adequately plead falsity or scienter for each category of statement. *See generally id*. I address falsity first, then scienter.

a. Falsity

A statement is false or misleading "if it would give a reasonable investor the impression of a state of affairs that differs in a material way from the one that actually exists." *Berson v. Applied Signal Tech., Inc.*, 527 F.3d 982, 985 (9th Cir. 2008). A plaintiff must specify "each statement alleged to have been misleading," the "reason or reasons why the statement is misleading," and "if an allegation . . . is made on information and belief[,]" "the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u-4(b)(1). "This means that a plaintiff must provide, in great detail, all the relevant facts forming the basis of her belief." *In re Silicon Graphics Inc. Sec. Litig.*, 183 F.3d 970, 985 (9th Cir. 1999). "[F]or statements to be actionable . . . under the PSLRA, they must have been false or misleading at the time they were made." *Macomb Cnty. Employees' Ret. Sys. v. Align Tech., Inc.*, 39 F.4th 1092, 1097 (9th Cir. 2022). "The fact that [a] prediction proved incorrect in hindsight does not make it untrue when made." *In re Oracle Corp. Sec. Litig.*, 627 F.3d 376, 390 (9th Cir. 2010).

i. MD Anderson trial

For the following reasons, I find that Luo adequately pleads falsity for (1) the efficacy of existing treatments and (2) the target for FDA approval, but not for (3) supposed baseless optimism.

1. Luo adequately pled falsity for statements relating to the efficacy of existing treatments.

Defendants argue that Luo improperly isolates statements Turgeon and Riga made in 2018 about the efficacy of existing cancer treatments and ignores that these statements were made in the context of tyrosine kinase inhibitors (TKIs). ECF No. 99 at 14. Specifically, they argue that these statements, in proper context, do not purport to address the FDA's threshold

for Pozi approval nor suggest that Pozi need only surpass TKIs to receive FDA approval. *Id.* I disagree.

The SAC alleges that "[d]espite their inside knowledge, Turgeon and Riga repeatedly falsely told investors that existing treatments had only '6% to 8%' or 'less than 10%' efficacy rates," ECF No. 104 at 6 (citing SAC, ECF No. 93 at ¶¶ 166–68, 171–72), when, in fact, Turgeon and Riga knew that "[b]ased on published data," the best existing therapy was "combination chemotherapy with VEGF inhibitor with an objective response rate of 22.9%[,]" and that it was "consistent with the FDA guidance" to judge Pozi "not versus other TKIs, but maybe against chemo or combinations." ECF No. 93 at 34.

Specifically, Luo alleges that Turgeon made the following public statements:

- May 3, 2018: "Current therapies only have less than 10% – I think a 6% to 10% response rate. So we have huge unmet need . . . ." *Id.* at ¶ 167.
- May 16, 2018: "[C]urrent TKIs and other therapies only have a 6% to 8% response rate, huge unmet need." *Id.* at ¶ 168.

And that Riga similarly said:

- March 6, 2018: "Current therapies are unsatisfactory, and there is significant unmet need in this patient population." *Id.* at ¶ 166.
- August 9, 2018: "[C]urrent available treatments is less than 10%." *Id.* at ¶ 171.
- November 8, 2018: Pozi "compares favorably to an overall response rate of less than 10% with available TKIs and a rate of less than 20% with the current standard of care second-line agents." *Id.* at ¶ 172.

Defendants argue that, based on the full context of these statements, a reasonable investor would not construe Turgeon or Riga as representing that the FDA would only compare Pozi to TKIs, nor regard these statements as addressing in any way the FDA's criteria for approval. ECF No. 99 at 14–18. Luo responds that "the plain language of the statements directly conflicts with Defendants' proposed interpretation." ECF No. 104 at 17. He points out that while

defendants claim that Turgeon and Riga limited their statements "only to TKIs," in reality, they repeatedly claimed the low efficacy applied to "current therapies" and "current available treatments" generally. *Id.* (citing SAC, ECF No. 93 at ¶¶ 166–69, 171–73). Luo also points out that despite the assertion that defendants "'neither stated nor implied anything regarding' FDA approval," at a minimum, Riga's August 9, 2018 claim that "current available treatments [are] less than 10%" was in direct response to a question from an analyst asking whether Spectrum had agreed with the FDA on a "response rate [and] PFS [Progression Free Survival] hurdle" for approval. *Id.* (citing ECF No. 93 at ¶ 171). I agree with Luo that these statements were misleading, even in context.

"Even if a statement is not false, it may be misleading if it omits material information." *See Khoja*, 899 F.3d at 1008. Although Turgeon's and Riga's statistics regarding TKIs may not have been false, they were misleading in the context of discussing Pozi. Indeed, even if reasonable investors did, in fact, understand that Turgeon and Riga were *only* referring to TKIs when citing the efficacy of existing, available therapies,[4] by stating that there was a "huge unmet need" in conjunction with these efficacy citations, a reasonable investor would understand Turgeon and Riga to be saying that Pozi would be judged only against other TKIs in its FDA approval process. "Once defendants choose to tout positive information to the market, they are bound to do so in a manner that wouldn't mislead investors, including disclosing adverse information that cuts against the positive information." *Schueneman v. Arena Pharms., Inc.*, 840 F.3d 698, 705–06 (9th Cir. 2016) (quoting *Berson*, 527 F.3d at 987) (cleaned up). By accusing Turgeon and Riga of failing to disclose that the FDA would be comparing Pozi not just against existing TKIs, but also against an existing combination treatment with an ORR of 22.9%,[5] the pleadings

[4] Which alone is questionable given phrasing such as "current TKIs ***and other therapies*** only have a 6% to 8% response rate". ECF No. 93 at 40 (emphasis added).

[5] Although defendants do not press this point, the court considers whether the complaint adequately alleges that Turgeon and Riga knew about the existing combination treatment with a 22.9% ORR and that Pozi would be compared against it at the time they made the relevant statements from May to November 2018. The complaint alleges that Turgeon and Riga definitively knew both things by December 19, 2018, when they made the statements that it was consistent with the FDA guidance to compare Pozi

sufficiently allege that Turgeon and Riga misled investors into thinking Pozi would be approved if it could top a 10% ORR. For those reasons, I find that Luo has sufficiently pled falsity as to this category of statements.

2. Luo adequately pled falsity for statements related to the target for FDA approval.

Defendants argue that Luo failed to allege any false or misleading statement in his claim that on May 16, 2018, Turgeon "misrepresented the level of ORR necessary for Pozi to achieve FDA approval". ECF No. 99 at 18 (quoting ECF No. 93 at ¶ 176). The SAC alleges that during a conference on May 16, Turgeon recounted that Pozi's MD Anderson study recently published a sixty-four percent confirmed ORR for its first eleven patients, then shared an anecdote from "[b]efore we started this trial" in which he had asked "thought leaders" for their views on what might constitute a "home run" in terms of the metrics desired for approval, and they responded that a "40% or more response rate" would be a "home run." ECF No. 100-5 at 6 ("I know as a drug developer, if I can get a 20% to 30% response rate, I can get a drug approved. But what's the home run I really want to look forward [to] and hope for?"). Luo alleges that while Turgeon touted a twenty to thirty percent ORR approval range to investors in 2018, he was aware that the FDA would require an observed ORR of thirty percent or more to approve Pozi. ECF No. 93 at 34 ("On April 28, 2020, Spectrum disclosed in a press release that '[b]ased on the FDA reviewed protocol, an observed ORR of 30%, with 17% as the lower bound for 95% CI was considered to be the clinically meaningful efficacy in our study.'").

not against other TKIs but against chemo or combinations. ECF No. 93 at 34. The SAC also alleges that on May 3, 2018, Riga admitted Spectrum was "in regular discussions with the FDA" while Turgeon likewise admitted on the same call that "[w]e know what the requirements are." *Id.* at 58. In this situation, the complaint succeeds in either plausibly alleging (1) that Turgeon and Riga were aware of what existing therapies Pozi would be measured against for approval when they misleadingly implied a lower standard, or (2) in plausibly alleging that Turgeon and Riga mislead investors by claiming that they knew what the FDA required of them—when they did not—and purporting to imply a specific, required success rate anyway.

Defendants argue that Turgeon's statements were merely a demonstration of "why there's so much excitement" in May 2018—because Pozi was at an ORR stage exceeding what these "thought leaders" had believed would be a "home run" (and more than doubling the alleged thirty percent threshold for FDA approval). *Id.* Defendants aver that a reasonable investor would not view Turgeon's anecdote as representing that the FDA would approve Pozi with an ORR of "20% to 30%" because Turgeon was recounting statistics that took place before the beginning of the MD Anderson trial and because the general metrics referenced "were no more than others' opinions or estimates" ("in your guys' eyes?"). ECF No. 99 at 18–19. I disagree.

Turgeon stated that "I know as a drug developer, if I can get a 20% to 30% response rate, I can get a drug approved", and then stated that "[w]hat I'm pleased to tell [you] on [the] early data, why there's so much excitement, [is] that we have 64% confirm response rate." ECF No. 100-5 at 6. A reasonable investor would understand Turgeon to be representing that the FDA would approve Pozi with an ORR of "20% to 30%[.]" Offering the information in the form of an "anecdote" from an earlier time does not save Turgeon. He affirmatively stated that he "know[s] as a drug developer, if [he] can get a 20% to 30% response rate, [he] can get a drug approved"—said in context of discussing Pozi, with no qualification that Pozi's approval ORR was different than this general approval range. This is particularly true when the next statement he made touts an initial sixty-four percent response rate—which certainly suggests the response rate is almost double of what the FDA will approve. Because Turgeon did not also disclose the higher ORR required for Pozi,[6] his statements on May 16 were plausibly misleading. *See Schueneman*, 840 F.3d at 705–06.

[6] The SAC alleges that the required ORR of thirty percent was known at least by April 28, 2020, ECF No. 93 at 34, but given Turgeon's and Riga's many statements assuring investors in 2018 that Spectrum was "in regular discussions with the FDA" and "[w]e know what the requirements are" *id.* at 58, Luo has successfully either plausibly pled that Turgeon knew about the thirty percent threshold in May 2018 when he misled investors into thinking it would be twenty to thirty percent or that Turgeon misled investors into thinking Spectrum was well versed in its requirements when it was not.

3. Luo failed to adequately plead falsity for statements related to "baseless optimism" for Pozi's BTD application.

Defendants argue that Luo's claim that in November 2018, Riga "incorrectly suggested that Pozi could still achieve BTD status" when Spectrum supposedly knew already that Pozi "did not meet the pre-specified criteria for BTD" is not supported by any factual allegation. ECF No. 99 at 19 (citing ECF No. 93 at ¶¶ 179–80). Luo's theory is that Spectrum knew Pozi needed to demonstrate more than a forty-three percent ORR in the MD Anderson trial to secure BTD status because Riga stated that he was aware of the "statistics that are expected [by the FDA]" and that Spectrum was "very much aligned with the [FDA]"—but BTD status was not ultimately granted. ECF No. 104 at 19 (citing ECF No. 93 at ¶ 180). Defendants argue that Luo has not sufficiently alleged that Riga's statements were false when made because the SAC has no factual support for the allegation that Spectrum "knew that BTD would require an ORR of over 43%." ECF No. 99 at 19 (citing ECF No. 93 at ¶ 180(a)). I agree with defendants.

A plaintiff must allege with particularity facts or evidence that show why the statement was false at the time it was made or that defendants knew or, with deliberate recklessness, disregarded that it was false. *Ronconi*, 253 F.3d at 431. Luo's complaint makes too many speculative leaps to survive the heightened pleading standard for this category of statements.

Luo alleges the following statements by Riga incorrectly suggested that Pozi could still achieve BTD status as follows:

> Sure, sure. David, we're thrilled to have submitted the application for BTD, and we remain very steadfast in our belief that there is an unmet need, and ***poziotinib is showing indications of being substantially better than currently available treatments. That's ultimately the criteria.*** Now the FDA will decide ultimately and where that goes, but there are multiple regulatory pathways besides BTD, like you had mentioned in the fast track setting and others that exist, but we are thrilled to have applied for that application and ***believe that the drug qualifies***.

ECF No. 93 at ¶ 178 (emphasis in SAC). Luo effectively asks the court to make the following logical leaps in concluding that these statements were misleading: (1) Riga was aware that the

FDA wanted an ORR of over forty-three percent when he made the statement and (2) Riga believed that the FDA would likely reject the BTD application because of the forty-three percent ORR results. This is too attenuated. Although Luo specifically alleges, for example, that the FDA communicated with Spectrum that it would require "an observed ORR of 30%" with respect to ultimately approving Pozi, Luo provides no such concrete allegation here outlining the FDA's expectations for BTD approval. In other words, the SAC does not provide any specific, contradictory information that would render Riga's November 2018 statement false or misleading as required by the PSLRA. Luo's speculation that Riga *must have known* that the qualifying ORR for BTD approval was higher than forty-three percent is too attenuated: Luo does not even allege that the FDA rejected the BTD application *because of* an inadequate ORR, as opposed to any other numbers of reasons. As currently pled, for all we know, the FDA required a forty-two percent or higher ORR for BTD approval and ultimately rejected the application due to side effects, or some unforeseen reason that Riga could not have predicted.

Simply put, Luo's speculation, even if not illogical—and even if necessary in the absence of access to the confidential FDA communications—is inadequate to survive the PSLRA's heightened pleading standard. *See Lake v. Zogenix, Inc.*, 2020 U.S. Dist. LEXIS 120965, at *20 (N.D. Cal. Jan. 24, 2020) ("Admittedly, plaintiffs are at a disadvantage when trying to plead precisely what the NDA [new drug application] did or did not contain, because they have not even seen the application, which is non-public and confidential . . . .The fact that the NDA is confidential and the RTF [refusal to file] letter has not been made public, however, does not relieve Plaintiffs of their obligation to meet the exacting pleading standards of the PSLRA."); *see also Bauer v. Eagle Pharms., Inc.*, 2017 WL 2213147, at *7 (D.N.J. May 19, 2017) ("While the Court acknowledges that Plaintiffs may lack information due to the confidentiality of the [FDA's critical response letter], this fact does not give Plaintiffs the authority to speculate. That is, speculation and conjecture will not support a claim under the PSLRA's heightened pleading standard."). Thus I dismiss this category of statements with leave to amend.

ii. ZENITH20 Trial

For the following reasons, I find that Luo fails in part to adequately plead falsity for alleged misstatements concerning defendants (1) expressing undue optimism for Pozi during the ZENITH20 trial and (2) referencing outdated results from the MD Anderson trial, and fails to adequately plead falsity for alleged misstatements concerning (3) the impact AEs had on C1 patients and efficacy results. I address the first two categories together and the third separately.

1. Luo fails in part to adequately plead falsity for the statements related to baseless optimism for Pozi's final approval and for statements relating to reference to outdated MD Anderson data.

Luo alleges that Turgeon and Riga made several false or misleading statements during the ZENITH20 trial that projected overinflated confidence in Pozi's ultimate success, including by referencing outdated MD Anderson results while neglecting to disclose that Turgeon and Riga contemporaneously knew that the incoming ORR results were not promising. ECF No. 93 at 64–72. Defendants argue that Luo fails to provide "particularized" allegations that Turgeon and Riga had contrary data when making optimistic statements regarding the success of the ZENITH trial and thus that this category of alleged misstatements should be dismissed. ECF No. 99 at 22–25. I agree with defendants in part.

The SAC alleges that defendants had access to the contemporaneous ZENITH20 trial data as it was "open label," which Lebel allegedly conceded meant Spectrum "could've looked at the data." ECF No. 93 at ¶ 98. The SAC further alleges that Turgeon and Riga referenced their access to and inspection of the data during various points of the ZENITH20 trial. *Id.* at ¶ 184 (Riga, on May 3, 2018: "we believe that pozi meets the criteria if the early data continues"; Turgeon, May 16, 2018: "I got an update yesterday on the enrollment" of the ZENITH20 trial; Lebel, on August 10, 2020: "Obviously, we're looking at data. It's an open-label study."); *see also Id.* at ¶¶ 187, 190. The SAC also provides corroborating accounts from confidential witness one (CW-1), who worked at a clinical site, and confidential witness two (CW-2), who worked at

Spectrum and oversaw the clinical sites, claiming that Spectrum controlled a database throughout the trial that housed real-time data, including safety statistics and final conclusions for each patient about the effectiveness of Pozi. *Id.* at ¶¶ 22–27, 36–38.

However, although Luo plausibly pleads that defendants had general access to the data in question, he fails to provide specific, particularized allegations that, at the time each defendant made his statement, he had accessed/reviewed specifically contradictory data or an internal report that rendered his statement false or misleading in the moment. *See Lipton v. Pathogenesis Corp.*, 284 F.3d 1027, 1036 (9th Cir. 2002) (reasoning that an adequate "complaint which purports to rely on the existence of internal reports would contain at least some specifics from those reports as well as such facts as may indicate their reliability" and that "negative characterizations of reports relied on by insiders, without specific reference to the contents of those reports, are insufficient . . ."). Simply pleading that the defendants had access to contrary data or potentially reviewed some contrary data without any specifics is insufficient to meet the heightened pleading burden at this stage.[7] *See, e.g.*, *Dearborn Heights*, 856 F.3d at 620 (finding allegations that defendant had access to data room, standing alone, insufficient to establish actual knowledge); *Dresner v. Silverback Therapeutics, Inc.*, 2023 WL 2913755, at *14 (W.D. Wash. Apr. 12, 2023) ("Plaintiffs point to no particularized facts that suggest that the data had been gathered and reviewed by the individual Defendants prior to the cutoff dates and the Court is unwilling to make such an inferential leap.").

[7] Not to mention, the complaint itself contains contradictory allegations regarding whether defendants were looking at the ZENITH20 data. ECF No. 93 at 86–87 (Lebel, October 2, 2019: "So, in theory we could look at the data – we could've looked at the data. **We decided at the Company that we did not want to look at the data.** We wanted to make sure that there's a central imaging lab. They are not influenced by what potentially investigators, etc., would know. And, we've also put in an independent data review committee, meaning expert lung cancer specialists were going to look at the data before we get to look at the data in the central imaging lab. So, that will allow us – for us to – **nobody is looking at the data for six months**. The last patient in, the first time that we're going to look at the data will be after six month's follow-up minimum.").

Although they serve as a helpful addition, the confidential informants' allegations do not carry the burden here. Neither informant can specifically allege that any defendant received and reviewed the data in question here. Indeed, CW-2's generalized knowledge of the availability of the data to Spectrum personnel and CW-1's belief that he/she was "pretty sure that higher-level people could see [the data]" simply do not cut it. ECF No. 93 at 105; *see City of Roseville Employees' Ret. Sys. v. Sterling Fin. Corp.*, 691 F. App'x 393, 396 (9th Cir. 2017) ("[M]issing from CW4's testimony is personal knowledge of what . . . executives knew or were specifically told"); *Ezzes v. Vintage Wine Ests., Inc.*, 2024 WL 895018, at *9–10 (D. Nev. Mar. 1, 2024) (discrediting allegations that confidential witnesses "reported their findings up the chain of command" where they "lack[ed] firsthand knowledge regarding what the Defendant Executives knew, or didn't know").

Because Luo cannot specifically allege that each defendant was reviewing the ZENITH20 data in real time, or at least prior to making each purportedly false or misleading statement, he fails to adequately plead falsity for statements related to baseless optimism for Pozi's final approval or related to references to outdated MD Anderson data.

However, I exclude from dismissal statements like Riga's on August 8, 2019, where he said: "[W]e feel really strong about . . . the data readout in Q4." ECF No. 93 at ¶ 188. Although the PSLRA's heightened pleading standard prevents the court from permitting allegations in this category without specific references to contrary data or reports each defendant reviewed prior to making his optimistic statement, defendants cannot have it both ways. Where a defendant specifically references data and expresses optimism, the court will allow these statements to survive because either the defendant (1) read the relevant data and expressed optimism despite knowing the new ORR numbers were not promising (i.e. falling short of the required thirty percent ORR) or (2) did not read the relevant data but was representing to shareholders that he had, and expressed unfounded/blind optimism, which in itself is misleading. For those reasons, I

dismiss in part and allow in part as outlined above these two categories of statements and do not allow amendment.

2. Luo fails to plead falsity for statements relating to "dramatic" AEs.

Defendants argue that the SAC contains no particularized allegations that the AEs were "[un]manageable" or "dramatic," even when viewed with the benefit of hindsight. ECF No. 99 at 25. I agree.

Luo provides figures showing that C1 and C3 ultimately reported dose interruptions and discontinuations at purportedly high percentages, ECF No. 93 at ¶ 203(a), but the SAC does not adequately specify or support how the statements made by Lebel on this front were misleading at the time he made them. His alleged misleading statements are:

- October 2, 2019:
  - The other thing we've done as well is, other than a lower increment of when you drop the dose. **Also additionally what we've done is we prophylax every patient for – against diarrhea**. One of the very common side effects when you use a TKI, it's a problem with the class, and actually is an indication that the drug blocks the EGFR receptor. They get rash and they get diarrhea or it impacts the gut. So we are prophylaxing all the patients against diarrhea. **Dr. Heymach was not doing that, so that should play in our favor.**

- March 10, 2020:
  - The confirmed objective response rate, as I mentioned to you, was 14.8%. That was below what we wanted. However, the patients who responded showed the duration of response that was 7.4 months. So that's a very good response rate. Meaning if you're one of the lucky patients to respond, your response last a significant amount of time clinically. So that's very important. The median progression-free survival was 4.2 months. **And the safety profile was in line with other second-generation EGFR tyrosine kinase inhibitor**.
  - So while we missed the primary endpoint, if you go to Slide 7, you will see there a waterfall plot that shows what I believe is unequivocal activity. The great majority of patients had tumor-size reduction. **And the other thing we've mentioned previously is that 2/3 of the patients had some form of dose interruption, could be as short as 1 day or as long as 2 weeks. And 2/3 had dose reduction. So we have 2/3 with interrupted therapy and 2/3 who had some form of dose**

> **reductions**. We will be presenting this data in much greater detail at the 11th Annual Congress on Pulmonary and Respiratory Medicine in Amsterdam next week, March 18, and that will be followed by a call in all–from management.

ECF No. 93 at 80–81.

Luo claims that Lebel's statements were materially false and misleading because "he incorrectly suggested that Spectrum could attain a manageable level of adverse events in Cohort 1" and that Lebel's assertions failed to disclose to unknowing investors that Pozi was causing AEs at levels far worse than the existing TKI "Tagrisso." ECF No. 93 at 81. The presumption in Luo's allegations is that Lebel's statements were misleading because he must have known that this level of AE incidence would bar Pozi's ultimate approval. But the allegations in the SAC does not support this. Although the allegations include statements that CW-1 and CW-2 believed the side effects were "a major problem," they do not explain why or how Lebel's specific statements were misleading based on what he knew or believed at the time. The most Luo alleges is that Lebel's statements were false or misleading because he knew about the high rate of AEs in C1. *Id.* This does not connect the dots, however. Indeed, the SAC does not allege, for example, that Lebel was aware of communications from the FDA that Pozi would not be approved *because of* the side effects, or that he knew the side effects would so hamper efficacy as to prevent approval.[8] In other words, Luo does not provide enough to demonstrate that Lebel knew or had reason to know his statements were false or misleading at the time.

Nor does Luo's related allegation that defendants failed to disclose that "Pozi would perform materially worse in Cohort 1" than it did at the "small single-center study at MD Anderson, a world-renowned cancer center with world-renowned oncologists[,]" in part

[8] Although not relying on it, the court also notes that documents provided by defendants appear to directly contradict this category of allegations. Indeed, C2 of the ZENITH20 trial reportedly bore out AEs akin to C1 and C3, yet the FDA permitted Spectrum to file a new drug application (NDA) based on that data, suggesting that Lebel had no reason to believe the incidence of AEs would be fatal. *See* Defs.' Ex. 14, ECF No. 100-14 at 5 (reporting the FDA meeting confirmed that C2 data can serve as the basis of an NDA submission and C2 experienced eighty-seven percent drug interruptions and twelve percent discontinuations).

because of AEs, hold water. ECF No. 93 at 73–74. Luo argues that this allegation is not "implausible" because Lebel admitted "[w]henever you have a single site study in general the data often is a little bit better than when you do a multi-center study." ECF No. 104 at 29 (citing ECF No. 93 at ¶ 185). However, nothing in the complaint or response to the motion to dismiss convinces the court why the absence of this "disclosure" was misleading. Spectrum is not required by the securities laws to disclose every single issue its drugs might face in the approval process. *Cf. In re Amylin Pharm., Inc. Sec. Litig.*, 2003 WL 21500525, at *8 (S.D. Cal. May 1, 2003) ("A company seeking FDA approval of a new drug clearly is not under any obligation to disclose every single issue raised by the FDA throughout the process."). I do not find here that Spectrum failing to affirmatively disclose the mere *possibility* that the multi-center study (ZENITH) may do a "little" worse than the single-sight study (MD Anderson)—even though born out in hindsight—constitutes a significant or misleading material statement. So these allegations are dismissed without leave to amend.

iii. Rolontis

For the following reasons, I find that Luo fails to adequately plead falsity for his Rolontis-related claims that (1) from March 15 to November 7, 2019, defendants misrepresented the voluntary nature of Spectrum's withdrawal of its first BLA submission, ECF No. 93 at ¶¶ 224–34, and that (2) from November 4, 2020, to May 13, 2021, defendants misled investors about the Hanmi facility's preparations for the FDA inspection, *id.* ¶¶ 235–47.

1. Luo fails to adequately plead falsity for statements concerning Spectrum's withdrawal of its first BLA submission.

Luo alleges that defendants incorrectly told investors that Spectrum chose to "voluntarily" withdraw its BLA, when it was, in fact, forced to withdraw the application to avoid a CRL (complete response letter) from the FDA rejecting the Rolontis application. ECF No. 93 at 96. Specifically, the SAC alleges that Turgeon made several misleading statements in 2019 regarding the voluntary nature of the BLA withdrawal but that on August 12, 2021, he

admitted: "So, [the FDA] told us, look[,] in this form we wouldn't accept it, so you can wait for us to not accept that or you could voluntarily fix this stuff and resubmit. And that's what happened." *Id.* at 96–97. Defendants argue this category of statements should be dismissed because "the challenged statements themselves accurately disclosed the very information Plaintiff alleges was omitted." ECF No. 99 at 34–36. I agree with defendants.

"Corporations are not required to phrase disclosures in pejorative terms." *Dalberth v. Xerox Corp.*, 766 F.3d 172, 186–87 (2d Cir. 2014). For that reason, disclosures of "factual information" do not become insufficient simply because they did "not use the eye-catching or negative phrasing that plaintiffs would have wished." *Singh v. Schikan*, 106 F. Supp. 3d 439, 448 (S.D.N.Y. 2015). Turgeon expressly told investors the BLA application was withdrawn due to the FDA's "request for additional" "required" information that Spectrum could not provide by the FDA's deadline. ECF No. 93 at ¶ 229. A reasonable investor would understand that the FDA was, in effect, requiring Spectrum to withdraw its application or face rejection. For that reason, though Turgeon did not use the negative phrasing that Luo might have wished, such as "ultimatum," these statements did, in fact, "reflect the actual state of [defendants'] affairs at the time the statements were made.'" *Glazer Cap. Mgmt., L.P. v. Forescout Techs., Inc.*, 63 F.4th 747, 767 (9th Cir. 2023). Therefore, I do not find that these statements are false or misleading and thus dismiss them without leave to amend.

2. Luo fails to adequately plead falsity for statements concerning the Hanmi facility's preparations for the FDA inspection.

Luo also alleges that defendants made false and misleading representations about their readiness for the FDA's inspection of the Hanmi manufacturing facility in South Korea without disclosing that "it fell well below FDA standards, and that Spectrum did not have the power or influence to bring it into compliance." ECF No. 93 at 99. Defendants argue that the facts alleged do not support that any of those alleged misstatements were false or misleading when made. ECF No. 99 at 36–37. I agree with defendants.

The alleged statements in question sound to the tune of comments like: "We are absolutely ready for this inspection. We've been ready for a long time. We welcome it"[9] and "we remain confident that our preparation with our partner Hanmi, should result in a positive outcome for this FDA plant inspection."[10] Luo alleges that statements such as these were false or misleading because "the Rolontis manufacturing facility maintained controls and procedures that deviated substantially from FDA requirements." ECF No. 93 at 101. However, the SAC fails to allege with particularity that Turgeon or Lebel believed or had reason to believe that the inspection was likely to fail at the time each made his statements.

Luo relies on two things to demonstrate falsity: (1) allegations from CW-2 that "although Spectrum wanted to supervise procedures at the Rolontis factory in South Korea, in reality Spectrum did not have control over what happened at Hanmi" and that Spectrum "failed [mock inspections] a couple of times . . . because, according to CW-2, 'the quality of plants and people [at Hanmi] were not up to industry standards[,]'" *id.*, and that (2) when the FDA actually inspected the plant, it found "ten independent deficiencies[.]" *Id.* Neither separately nor together do these allegations carry Luo's burden to plead with specificity that each defendant knew their statement was false or misleading at the time made.

First, Luo does not plead that CW-2 had particularized firsthand knowledge of what was happening at Hanmi during the relevant period. When a complaint relies on confidential witnesses, secondhand knowledge is insufficient. *In re NVIDIA Corp. Sec. Litig.*, 768 F.3d at 1058. CW-2 did not work at the Hanmi facility nor are there any particularized allegations that he/she communicated directly with any employees or personnel there. Further, CW-2's allegations regarding the failed mock inspections are outdated. He/she left the company in March of 2020; Turgeon and Lebel made the statements in question starting in November of 2020. In other

[9] Turgeon on November 4, 2020. ECF No. 93 at 100.
[10] Lebel on May 13, 2021. ECF No. 93 at 103.

words, for all that CW-2 knows, Spectrum had been passing its mock inspections for months prior to Turgeon's and Lebel's statements.

Nor does the fact that the FDA found multiple deficiencies at the actual inspection mean that Turgeon and Lebel must have known the facility was not ready or that it was likely to be deficient. *See In re Oracle Corp. Sec. Litig.*, 627 F.3d at 389–90) ("The fact that [defendant's] forecast turned out to be incorrect does not retroactively make it a misrepresentation.") (citing *In re VeriFone Sec. Litig.*, 11 F.3d at 871) ("The fact that the prediction proves to be wrong in hindsight does not render the statement untrue when made.")). Although a broad, rational inference could be drawn from the results of the inspection, the PSLRA demands more particularity than that. Because Luo is unable to point to any specific, contrary information of which Turgeon or Lebel were aware that the Hanmi facility was not ready for inspection at the time their statements were made, I dismiss this category of statement for lack of falsity with leave to amend.

b. Scienter

Scienter is "a mental state that not only covers intent to deceive, manipulate, or defraud, but also deliberate recklessness." *Schueneman*, 840 F.3d at 705. "The PSLRA's 'strong inference' requirement has teeth. It is an 'exacting' pleading obligation that 'present[s] no small hurdle for the securities fraud plaintiff.'" *Nguyen v. Endologix, Inc.*, 962 F.3d 405, 414 (9th Cir. 2020) (citations omitted). Thus, to establish a strong inference of deliberate recklessness,

the plaintiff must plead "a highly unreasonable omission, involving not merely simple, or even inexcusable negligence, but an extreme departure from the standards of ordinary care, and which presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious that the actor must have been aware of it." *Zucco*, 552 F.3d at 991. In determining whether each defendant had the requisite scienter, courts "must consider plausible, nonculpable explanations" for defendants' conduct, and determine "whether all of the facts alleged, taken collectively, give rise to a strong inference of scienter." *Tellabs, Inc.*, 551 U.S. at 323.

Because I do not find that Luo adequately pled falsity for the Rolontis allegations, I do not address scienter for that portion of the complaint. I consider only whether Luo adequately pled scienter related to his surviving Pozi claims. I find that while it is a close issue, Luo provides enough that, when considered holistically, the SAC sufficiently pleads scienter as to Turgeon.

Luo's broad theory of scienter goes as follows: in January 2019, Spectrum entered into an agreement to sell its portfolio of seven FDA-approved hematology/oncology products to Acrotech Biopharma and unloaded all of Spectrum's assets other than Pozi and Rolontis. ECF No. 93 at 22. Thus, because neither Pozi nor Rolontis were FDA-approved, Spectrum had no revenue instream other than underwritten or at-the-market (ATM) offerings. *Id.* As Luo alleges, with resources dwindling and no way to earn revenue, "in a desperate attempt to promote their products and solicit interest for their fundraising efforts, [d]efendants turned to fraud." *Id.* at 10. Indeed, Luo alleges that, despite knowing that Pozi was falling well short of the required ORR for approval during C1 of the ZENITH20 trial as early as March 10, 2019, Turgeon, Riga, and Lebel were making public statements expressing optimism about the success of C1 simultaneously with Spectrum's first ATM offering which began on April 5, 2019. *Id.* at 133. Simultaneously with that offering, Turgeon sold over 40,000 personal shares of stock on May 16, 2019, and June 6, 2019, amounting to $340,000 in proceeds.[11] *Id.* Luo then alleges that after two

[11] Although defendants argue that these stock sales are not evidence of scienter because they were made pursuant to tax withholding obligations or 10b5-1 trading plans, as explained *infra*, I do not consider exhibits 32 or 33 for the truth of the matter asserted. In other words, at this stage, I do not engage in a summary-judgment-like analysis of the circumstances under which such trades were made but accept as true Luo's well pled allegations. Further, I find the timing, amounts and percentages of Turgeon's trades notable and inconsistent with his "prior trading history." *See Nursing Home Pension Fund, Loc. 144 v. Oracle Corp.*, 380 F.3d 1226, 1232 (9th Cir. 2004). Indeed, the smaller number of shares sold of his two large sales in 2020 right before the public learned about the failed Pozi ORR (150,899 shares) is still over four times larger than the largest amount of shares he had sold in the three years prior (36,311 shares). ECF No. 93 at 140–41. In fact, most of Turgeon's sales in 2018 were well below 10,000 shares at a time (e.g., 3,100 shares, 6,307 shares, 1,944 shares). *Id.* Thus, while not sufficient alone to establish scienter, I find Turgeon's trading history to be "dramatically out of line with prior trading practices" and done "at times calculated to maximize personal benefit from undisclosed inside information," *Police Ret. Sys. of St. Louis v. Intuitive Surgical, Inc.*, 759 F.3d 1051, 1063–64 (9th Cir. 2014) (internal citations omitted), and thus probative of scienter.

more ATM offerings and a public offering during C3, Turgeon sold 162,472 shares on November 18, 2020, for about $670,000, constituting 24% of his holdings at the time and then about a month later, sold 150,899 shares for $709,225, constituting 29% of his holdings just days before Spectrum announced the non-successful final ORR of 27.8% on December 22, 2020. *Id.*

Luo also points to the "unexpected departures" of CEO Turgeon and CFO Gustafson shortly after the end of the class period. *Id.* at 113. Luo alleges that Turgeon "retired" on December 1, 2021, less than four years after taking over as CEO, and that Gustafson followed shortly thereafter on February 23, 2022. *Id.* Luo alleges that Spectrum never provided a "benign" reason for the sudden exodus and that these same two executives made massive and uncharacteristic sales of Spectrum common stock in the days leading up to Spectrum's announcement that C3 had failed, then departed the company just months after the truth was revealed to the market. *Id.*

Defendants object that Luo's theory—that the individual defendants "'were promising [BTD or approval] for a medical device application they knew was 'unapprovable'—is 'irrational' and 'make[s] [no] sense.'" ECF No. 112 at 11 (citations omitted). But that misses the bigger picture. For one, the individual defendants could well have hoped that approval for either the BTD application or the drug itself may be forthcoming, even if not likely, and wanted to maximize fundraising at the shareholders' expense and risk. *See Makor Issues & Rts., Ltd. v. Tellabs Inc.*, 513 F.3d 702, 710 (7th Cir. 2008) ("[t]he fact that a gamble – concealing bad news in the hope that it will be overtaken by good news – fails is not inconsistent with its having been a considered, though because of the risk a reckless, gamble")). But more to the point, the allegations are consistent with a narrative where, regardless of whether the executives of Spectrum believed Pozi would succeed, Turgeon, in particular, intended to personally profit either way by dumping his shares and then abandoning the company if things went wrong. The SAC has allegations consistent with this theory and sufficient that, when considered holistically

in context with the nature of the misleading statements Turgeon made during the Pozi trials, establish scienter for Turgeon. *E. Ohman J v. NVIDIA Corp.*, 81 F.4th 918, 940 (9th Cir. 2023) ("Even if no single allegation, standing alone, is 'sufficient to give rise to a strong inference of scienter,' a holistic review of all the allegations may 'combine to give rise to a strong inference of scienter.'") (quoting *Glazer*, 63 F.4th at 766). Because Gustafson does not appear to have made any of the alleged misstatements for Pozi, the issue of scienter is moot for him. While the statements themselves that Riga and Lebel made surrounding Pozi are suggestive of scienter given it appears both defendants were aware of contrary information when they spoke, alone the statements do not create a "strong inference" of scienter sufficient to meet the PSLRA's exacting scienter standard. Thus I find that Luo adequately pleads scienter only for Turgeon for the 10(b) claim.

2. Section 20(a) of the Exchange Act (counts II and III)

Defendants argue that Luo's derivative Section 20(a) and 20A claims "may be dismissed summarily" because Luo "fails to adequately plead a primary violation of section 10(b)." ECF No. 35 (quoting *In re Allied Nevada Gold Corp.*, 2016 WL 4191017, at *15 (D. Nev. Aug. 8, 2016); *see In re Facebook, Inc. Sec. Litig.*, 87 F.4th 934, 947 (9th Cir. 2023)). But, part of Luo's section 10(b) claim survives, so I reject defendants' limited argument for dismissal of the Section 20(a) claims. Luo's Section 20(a) claims survive.

IV. Conclusion

Taking as true all material allegations in the complaint, along with all reasonable inferences to be drawn from them and construing the complaint in the light most favorable to the Trust, I find that Luo's 10(b) claim regarding the Pozi allegations survives in part as outlined above, and his Section 20(a) claims survive in full.

It is hereby ordered that defendants' motion to dismiss **[ECF No. 99] is GRANTED in part and DENIED in part** as outlined in this order.

It is further ordered that defendants' request for judicial notice **[ECF No. 101] is GRANTED in part and DENIED in part** as outlined in this order.

It is further ordered that Luo's motion to strike **[ECF No. 107] is GRANTED in part and DENIED in part**. The clerk is court is kindly instructed to strike exhibit 1 (ECF No. 100-1) to the Declaration of John B. Lawrence.

It is further ordered that Lou's motion for leave to file supplemental authority **[ECF No. 114] is DENIED**.

This matter is referred to the magistrate judge for a settlement conference. Local Rule 16-5. If the parties are unable to reach an agreement resolving the claim, Luo will have the option to amend his complaint within fifteen days of the failed settlement conference.

Dated: October 7, 2024

Cristina D. Silva
United States District Judge